

 <small>Substitute Form PTO-1449 (Modified)</small> <small>(37 CFR §1.98(b))</small>	Information Disclosure Statement by Applicant (Use several sheets if necessary)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-150003	Application No. 10/010,283
			Applicant Carl-Axel Bauer <i>et al.</i>		
			Filing Date November 13, 2001	Group Art Unit 1617	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	CA						

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	CB						

Other Documents (include Author, Title, Date, and Place of Publication)							
Examiner Initial	Desig. ID	Document					
✓	CC	<i>Compendium Suisse des Medicaments</i> , 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 2-3, 419-420, 866 (in French)					
✓	CD	<i>Compendium Suisse des Medicaments</i> , 18th Ed. 1997, compiled June 1996, pages 5, 849-851 and 1635-1636 (in French)					
✓	CE						
	CF						

Examiner Signature	Date Considered
EXAMINER: Initials of citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

**Information Disclosure Statement
by Applicant**
(Use several sheets if necessary)
(37 CFR §1.98(b))

Substitute Form PTO-1449 (Modified)	NOV 04 2005 U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-150003	Application No. 10/010,283
		Applicant Carl-Axel Bauer <i>et al.</i>	
		Filing Date November 13, 2001	Group Art Unit 1617

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	BA						

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
✓	BB	WO 97/11783	04/03/1997	WIPO			

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
✓	BC	"American Thoracic Society: Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease," <i>Am. J. Respir. Care Med.</i> 152:S77-S121 (1995)
✓	BD	"Atemstillstand" <i>Pschyrembel Klinisches Wörterbuch</i> (2002) (in German)
	BE	Auffarth <i>et al.</i> , "Effects of inhaled budesonide on spirometric values, reversibility, airway responsiveness, and cough threshold in smokers with chronic obstructive lung disease" <i>Thorax</i> 46:372-377 (1991)
	BF	Barnes, "Inhaled steroids in COPD" <i>The Lancet</i> 351:766-767 (1998)
	BG	Basic Reference Manual, vol. 1, revised ed. of 1988, issued by IMS International
	BH	"Bronchodilators and anti-inflammatories," <i>Monthly Index of Medical Specialities (MIMS)</i> 242-256 (09/1997)
	BI	Boyd <i>et al.</i> , "An Evaluation of Salmeterol in the Treatment of Chronic Obstructive Pulmonary Disease (COPD)," <i>Eur. Resp. J.</i> 10:815-821 (1997)
	BJ	Burge <i>et al.</i> "Randomised, double blind, placebo controlled study of fluticasone propionate in patients with moderate to severe chronic obstructive pulmonary disease: the ISOLDE trial," <i>British Med. J.</i> 320:1297-1303 (2000)
	BK	Davies <i>et al.</i> , "Oral corticosteroid trials in the management of stable chronic obstructive pulmonary disease," <i>Q. J. Med.</i> 92:395-400 (1999)
	BL	"Disorders of the Airways," <i>Current Medical Diagnosis and Treatment 1997</i> 36 th ed. pages 241-255, Stamford, CT: Appleton and Lange (1997)
	BM	Dompeling <i>et al.</i> , "Slowing the deterioration of Asthma and Chronic Obstructive Pulmonary Disease Observed during Bronchodilator Therapy by Adding Inhaled Corticosteroids," <i>Ann. Intern. Med.</i> 118(10):770-778 (1993)
	BN	Engel <i>et al.</i> , "A trial of inhaled budesonide on airway responsiveness in smokers with chronic bronchitis" <i>Eur. Respir. J.</i> 2:935-939 (1989)
	BO	Fabbri <i>et al.</i> , "Global Strategy for the Diagnosis, Management and Prevention of COPD: 2003 update" <i>Eur. Respir. J.</i> 22:1-2 (2003)
✓	BP	Flenley, "Chronic Obstructive Pulmonary Disease," <i>Disease-A-Month</i> 34:549-599 (1988)
✓	BQ	"Foradil" <i>Compendium Suisse des Medicaments</i> , Supplement 1a pages 7-8 (1991) (in French)

Examiner Signature	Date Considered
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Substitute Form PTO-144 NOV 04 2003 S. Department of Commerce (Modified)		Attorney's Docket No. 06275-150003	Application No. 10/010,283
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Carl-Axel Bauer <i>et al.</i>	
		Filing Date November 13, 2001	Group Art Unit 1617
(37 CFR §1.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
✓	BR	"Foradil," <i>Compendium Suisse des Medicaments</i> , 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 419-420, 866 (in French)
✓	BS	"Foradil," <i>Compendium Suisse des Medicaments</i> , 18th Ed. 1997, compiled June 1996, pages 849-850 and 1635 (in French)
	BT	"Foradil" Patient information leaflet, published by IKS, Switzerland (12/1990) (in French)
	BU	Gibson <i>et al.</i> , <i>Respiratory Medicine</i> Table of contents (2002)
	BV	"GOLD: Global Initiative for Chronic Obstructive Lung Disease," Executive Summary; National Institutes of Health, National Heart Lung and Blood Institute, NIH Publication No. 2701A, pages 1-30 (03/2001)
	BW	"GOLD: Global Initiative for Chronic Obstructive Lung Disease; Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease," based on April 1998 NHLBI/WHO Workshop, pages 1-100 (2004 Update)
	BX	Jeffery "Structural and inflammatory changes in COPD: a comparison with asthma" <i>Thorax</i> 53:129-136 (1998)
	BY	Keatings <i>et al.</i> , "Effects of Inhaled and Oral Glucocorticoids on Inflammatory Indices in Asthma and COPD" <i>Am. J. Respir. Crit. Care Med.</i> 155:542-548 (1997)
	BZ	Kerstjens <i>et al.</i> , "A Comparison of Bronchodilator Therapy with or without Inhaled Corticosteroid Therapy for Obstructive Airways Disease," <i>New Eng. J. Med.</i> 327:1413-1419 (1992)
	BAA	Leff <i>et al.</i> , "Therapeutic Regimens in Chronic Obstructive Pulmonary Disease," <i>Pulmon. Crit. Care Pharmacol. Therapeut.</i> Ch. 86:837-844 (1996)
	BBB	Niewoehner <i>et al.</i> , "Effect of Systemic Glucocorticoids on Exacerbations of Chronic Obstructive Pulmonary Disease" <i>New Eng. J. Med.</i> 340(25):1941-1947 (1999)
	BCC	Norman, "COPD: New Developments and Therapeutic Opportunities" <i>Drug News Perspect.</i> 11(7):431-437 (1998)
	BDD	Pauwels <i>et al.</i> , "Long-Term Treatment with Inhaled Budesonide in Persons with Mild Chronic Obstructive Pulmonary Disease Who Continue Smoking" <i>N. Eng. J. Med.</i> 340:1948-1953 (1999)
	BEE	Postma, "Inhaled therapy in COPD: what are the benefits?" <i>Respiratory Medicine</i> 85:447-449 (1991)
	BFF	"Pulmicort" ABPI Data Sheet Compendium, p. 146-147 (1995/1996)
	BGG	Schultze-Werninghaus, "Multicenter 1-Year Trial on Formoterol, a New Long-Acting β_2 -Agonist, in Chronic Obstructive Airway Disease," <i>Lung Suppl</i> :83-89 (1990)
	BHH	Siafakas <i>et al.</i> , "Optimal Assessment and Management of Chronic Obstructive Pulmonary Disease (COPD)," <i>Eur. Respir. J.</i> 8:1398-1420 (1995)
	BII	Soriano <i>et al.</i> , "Inhaled Corticosteroids with/Without Long-Acting β -Agonists Reduce the Risk of Rehospitalization and Death in COPD Patients," <i>Am. J. Respir. Medic.</i> 2:67-74 (2003)
	BJJ	Stalenheim <i>et al.</i> , "Efficacy and Tolerance of a 12-Week Treatment with Inhaled Formoterol in Patients with Reversible Obstructive Lung Disease," <i>Respiration</i> 61:305-309 (1994)
✓	BKK	Stedman's Medical Dictionary, 25 th ed., Baltimore: Williams and Wilkins; page 428
✓	BLL	Szafranski <i>et al.</i> , "Efficacy and safety of budesonide/formoterol in the management of chronic obstructive pulmonary disease" <i>Eur. Respir. J.</i> 21:74-81 (2003)

Examiner Signature	Date Considered
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EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)		NOV 24, 2001 U.S. Patent and Trademark Office	Attorney's Docket No. 06275-150003	Application No. 10/010,283
Information Disclosure Statement by Applicant <small>(Use several sheets if necessary)</small> <small>(37 CFR §1.98(b))</small>		Applicant Carl-Axel Bauer et al.		
		Filing Date November 13, 2001	Group Art Unit 1617	

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
2	BMM	Trechsel, "Foradil in medical practice; 7 case studies" Ciba Geigy (1992)
1	BNN	Van Schayck et al., "Do patients with COPD benefit from treatment with inhaled corticosteroids?" <i>Eur. Respir. J.</i> 9:1969-1972 (1996)
1	BOO	Vestbo et al., "Long-term effect of inhaled budesonide in mild and moderate chronic obstructive pulmonary disease: a randomised controlled trial," <i>Lancet</i> 353:1819-1823 (1999)
4	BPP	Watson et al., "Failure of Inhaled Corticosteroids to Modify Bronchoconstrictor or Bronchodilator Responsiveness in Middle-Aged Smokers with Mild Airflow Obstruction" <i>Chest</i> 101(2):350-355 (1992)
2	BQQ	Weiner et al., "Inhaled Budesonide Therapy for Patients with Stable COPD," <i>Chest</i> 108:1568-1571 (1995)

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NO. 7012 P. 2/3

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 06275-150003	Application No. 09/670,457
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Carl-Axel Bauer et al.	
		Filing Date	Group Art Unit 1614
(37 CFR §1.98(b))			

U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date if Appropriate
	AA	5,795,564	8/18/1998	Aberg et al.			03/07/1996
	AB						

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Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	AC	WO 93/1173	06/24/93	PCT				
	AD	0 416 950 A1	03/13/1991	Europe				
	AE	0 416 951 A1	03/13/1991	Europe				

Other Documents (Include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	JAF	CA 126:259329 Renkema et al.
	AG	C. Wyser et al., "Neue Aspekte in der Behandlung des Asthma bronchiale und chronisch obstruktiver Lungenkrankheiten", 1997, Schweiz Med Wochenschr, Volume 127 page 885-page 890
	AH	Jean H. Marsac, Fotis D. Vlastos, and Jacques G. Lacronique "Inhaled beta adrenergic agonists and inhaled steroids in the treatment of asthma" Annals of Allergy September 1989, Vol. 63, number 3, pages 220-224
	AI	Francis P.V. Maesen, M.D., Ph.D., F.C.C.P., Joseph J. Smeets, Hendrik L. L. Gubbelmans, M.D., and Petra G. M. A. Zweers, M.D. "Formoterol in the Treatment of Nocturnal Asthma" Chest 98 4 October 1990 pages 886-870
	AJ	Francis P.V. Maesen, M.D., Ph.D., F.C.C.P., Joseph J. Smeets, Hendrik L. L. Gubbelmans, M.D., and Petra G.M. A. Zweers, M.D. "Bronchodilator Effect of Inhaled Formoterol vs. Salbutamol Over 12 Hours" Chest 97/3/March 1990
	AK	Romain A. Pauwels, M.D., Claes-Goran Lofdahl, M.D., Peter J. Barnes, M.D., and Anders Ullman, M.D. "Effect of Inhaled Formoterol and Budesonide on Exacerbations of Asthma" Vol. 337 Number 20, November 13, 1997
	AL	Curriculum Vitae of Charles Richard William Beasley
	AM	Statutory Declaration of Charles Richard William Beasley
	AN	New Ethicals Catalogue, December 1990, No. 3 p. 50
	AO	Additive effects of Budesonide and Formoterol in Reducing Severe Asthma Exacerbations Over 12 Months, O'Byrne et al. On behalf of international study group and Astra Draco AB Lund Sweden
	AP	Effect of Inhaled Formoterol and Budesonide on Exacerbations of Asthma, Pauwels et al., Massachusetts Medical Society, November 13, 1997, Vol. 337, Number 20, p. 1405
	AQ	Response by Astra to EPO, dated November 22, 1995

Examiner Signature	Date Considered
	11/30/06

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Substitute Disclosure Form (PTO-1449)

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NO. 7012 P. 3/3

Sheet 1 of 1

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Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Carl-Axel Bauer et al.	
		Filing Date	Group Art Unit
(37 CFR §1.98(b))			

U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA						
	AB						
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	AG						
	AH						
	AI						
	AJ						
	AK						

Foreign Patent Documents or Published Foreign Patent Applications

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	AL							
	AM							
	AN							
	AO							
	AP							

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AQ	Huib A.M. Kerstjens, MD., et al. "A Comparison of Bronchodilator Therapy with or without Inhaled Corticosteroid Therapy for Obstructive Airways Disease" November 12, 1992, The New England Journal of Medicine, Vol. 327 number 20, pages 1413-1419.
	AR	
	AS	
	AT	

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